DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 02D–0258]

Revised Guidance for Industry on Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a revised guidance for industry entitled "Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations." This guidance revises the guidance of the same name that issued in October 2000.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the revised guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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FOR FURTHER INFORMATION CONTACT: Aida L. Sanchez, Center for Drug Evaluation and Research (HFD–650), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5847.

SUPPLEMENTARY INFORMATION:

I. Background

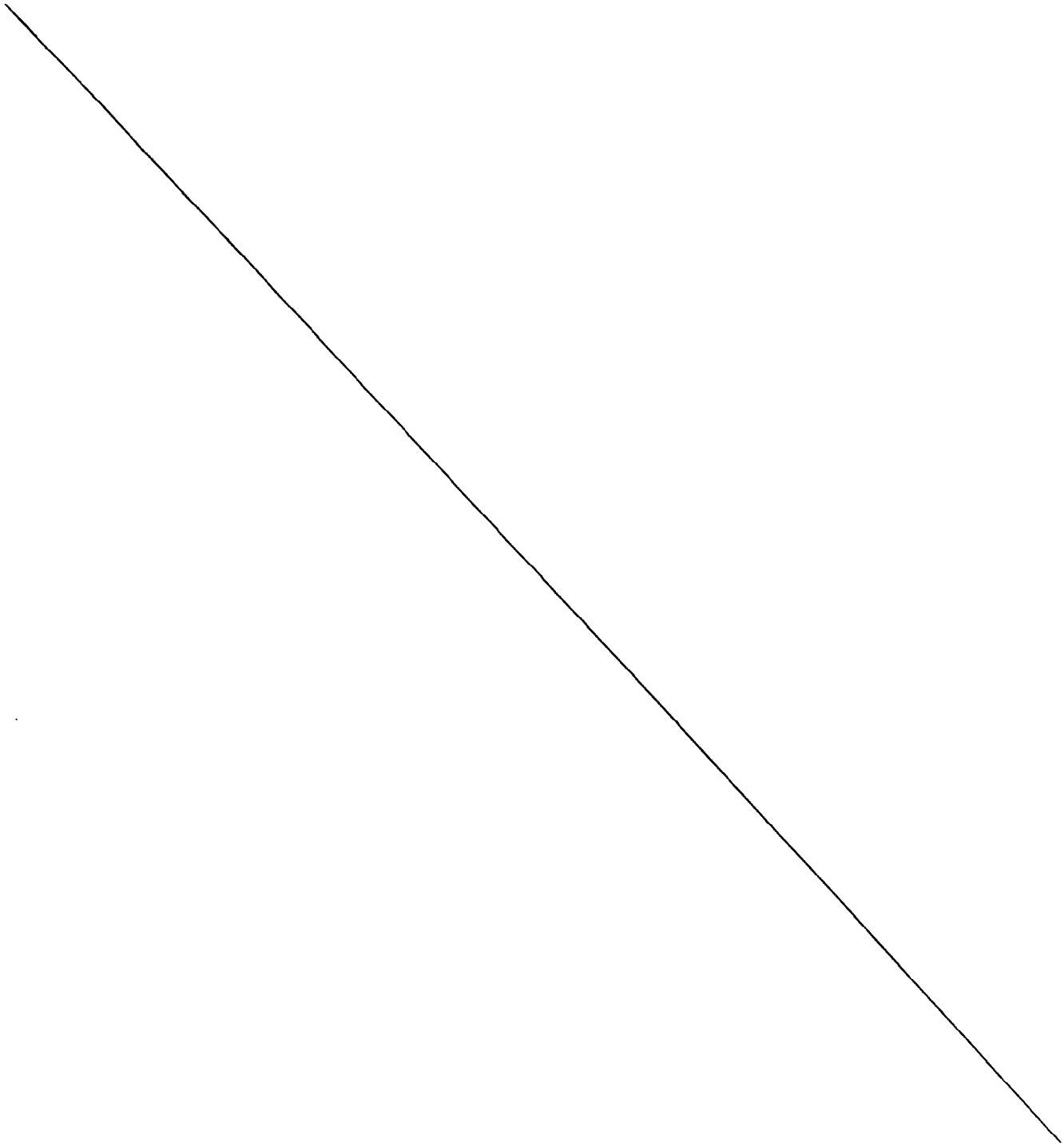
The agency is announcing the availability of a revised guidance for industry entitled "Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations." This is a revision of the guidance of the same name issued in October 2000. The guidance is intended to provide information to sponsors and/or applicants planning to include bioavailability (BA) and bioequivalence (BE) information for orally administered drug products in investigational new drug applications (INDs), new drug applications (NDAs), and abbreviated new drug applications (ANDAs) and their supplements. Since the October 2000 guidance was issued there have been changes due to the following: (1) Agency thinking based, in part, on input from the Advisory Committee for Pharmaceutical Science, (2) experience with the guidance, and (3) outside comments. Therefore, the agency decided to revise the guidance.

A draft of the revision was published in the **Federal Register** of July 11, 2002, (67 FR 45983). Comments on the draft submitted to the docket were considered carefully during the finalization of this guidance. Only minor, clarifying editorial changes have been made to this final version.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two

copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: March 10, 2003.

March 10, 2003.

William K. Hubbard,
Associate Commissioner for Policy and Planning.

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